

Remarks

Entry of the foregoing and reconsideration of the application identified in caption as amended, pursuant to and consistent with the Rules of Practice in Patent Cases, and in light of the remarks which follow, is respectfully requested.

By the present amendment, claim 1 has been amended and claim 3 has been canceled so that claims 1, 2, and 4-27 will remain pending. The amendment to claim 1 finds support in the specification at least at page 3, lines 20 to 21 and page 21, lines 23 to 24 of the application as filed. Accordingly, no new matter has been presented by the proposed amendment. Presently, claims 1-4, 11, 12, 14, 15-20 and 27 are being examined and claims 5-10, 13, and 21-26 have been withdrawn from consideration as being directed to non-elected inventions.

Claims 1-4, 11, 12, 14-16, 18-20, and 27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,352,439 to Norfleet et al. ("Norfleet"). This rejection is respectfully traversed.

The present invention pertains to compositions for the desensitization of teeth including an acid and an organic polymer having the recited properties. It has been found by the present inventors that these compositions deeply penetrate into dentinal tubules. By reaction with dentinal fluid proteins they form massive plugs and thus reduce the sensitivity of the teeth (see page 20, lines 1 to 8 and 17 to 23 of the present application). To achieve the desired formation of a plug, it is necessary to use acids having protein and calcium precipitating properties. The resulting formation of such plugs is surprising since acids usually have a sensitizing effect rather than a desensitizing effect (see page 20, lines 7 to 8 of the present application).

The inventors have demonstrated that the compositions of the present invention result in the formation of massive plugs which deeply penetrate into dentinal tubules (see page 36, Example 8, in particular lines 31 to 35 in combination with Figures 3 and 5; page 36, line 38 to page 37, line 8; and Figure 6 of the present application) even if the natural pressure of dentinal fluid is simulated. The desensitization agents of the present invention result in a long-lasting desensitization effect.

Formation of these plugs cannot be explained by the mere agglomeration of the polymers contained in the compositions. The experiments of the inventors noted above clearly show that the simultaneous precipitation of polymer, dentinal fluid proteins and calcium is responsible for the formation of the plugs.

In contrast, Norfleet does not disclose or suggest the present invention. Rather, Norfleet discloses oral compositions, such as a tooth paste, including an effective anti-tartar proportion of polyphosphate, and a desensitizing or tooth pain inhibiting proportion of a tooth pain inhibiting potassium salt (see column 1, lines 54 to 59). Preferably the compositions include a potassium salt of an anionic polymeric polycarboxylate (see column 1, lines 64 to 68). These compositions may additionally contain diphosphonic acids and phosphonoalkane carboxylic acids or their alkali metal salts (see column 2, lines 8 to 12). Copolymers, if initially in acidic form, are neutralized to a pH in the range of 6 to 8, preferably 7 (see column 10, lines 3 to 6). Moreover, the pH of the overall composition is preferably also within the range of 6 to 8, more preferably 6.5 to 7.5 (see column 10, lines 25 to 26). Norfleet theorizes that the presence of potassium ion in the composition aids in desensitizing the teeth in toothpastes and other oral compositions so that the teeth feel less pain when brushed (see column 2, lines 17 to 21). Accordingly, Norfleet does not teach or suggest compositions having a pH within the claimed range of from 1 to 4.

According to Norfleet, acid components are neutralized and the pH of the compositions is adjusted to be in the range of 6 to 8. There is no reason to modify the compositions of Norfleet to adjust the pH within the claimed range of from 1 to 4. The compositions of Norfleet therefore teach away from the claimed invention and do not possess free acid having protein and calcium precipitating properties.

Withdrawal of the record rejection of claims 1, 2, 4, 11, 12, 14-16, 18-20, and 27 under 35 U.S.C. § 102(b) as being anticipated by Norfleet and allowance of all claims is respectfully requested.

Claims 3 and 17 stand rejected under 35 U.S.C. § 103(a) as being obvious over Norfleet in view of U.S. Patent No. 5,750,145 to Patell ("Patell"). This rejection is respectfully traversed.

Patell pertains to stabilized pharmaceutical compositions including gelatin-coated pharmaceutically active dosage units containing a therapeutically active ingredient which is subject to hydrolysis on storage as a result of moisture in the air or in one or more of the components of the dosage unit. Patell is especially concerned with the stabilization of analgesics such as gelatin-coated aspirin tablets (see column 1, lines 5 to 12). Patell is cited for teaching film-forming agents. However, Patell in no way teaches or suggests adjusting the pH of the compositions disclosed by Norfleet in the claimed range of from 1 to 4. Accordingly, Patell fails to make up for the deficiencies of the Norfleet

disclosure noted above. For at least these reasons Applicants submit that even the proposed combination of Norfleet and Patell does not render obvious the present invention.

Withdrawal of the record rejection based on the combination of Norfleet and Patell and allowance of all claims is respectfully requested.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is hereby earnestly solicited.

Respectfully submitted,

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